**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

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| NORTH MIAMI BEACH GENERAL EMPLOYEES RETIREMENT FUND, *et al.*, | Case No. 10 C 6514 |
| Plaintiffs, | Hon. Edmond E. Chang |
| vs. | |
| ROBERT L. PARKINSON, *et al*., | |
| Defendants, | |
| -and- | |
| BAXTER INTERNATIONAL INC., | |
| Nominal Defendant. | |

**INDEX OF EXHIBITS**

**Exhibit A**

Declaration of Timothy A. Ulatowski in Support of Lead Plaintiff's Amended Consolidated Class Action Complaint for Violation of the Federal Securities Laws

**Exhibit B**

Declaration of Betty Collins in Support of Lead Plaintiff's Amended Consolidated Class Action Complaint for Violation of the Federal Securities Laws

# EXHIBIT A

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ILLINOIS

EASTERN DIVISION

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| CITY OF LAKELAND EMPLOYEES PENSION PLAN, Individually and on Behalf of All Others Similarly Situated,<br><br>Plaintiff,<br><br>vs.<br><br>BAXTER INTERNATIONAL INC., et al.,<br><br>Defendants. | Case No. 1:10-cv-06016<br><br>CLASS ACTION<br><br>DEMAND FOR JURY TRIAL |

**DECLARATION OF TIMOTHY A. ULATOWSKI IN SUPPORT OF LEAD PLAINTIFF'S AMENDED CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS**

I, Timothy A. Ulatowski, declare:

1. I served as the Director of the Office of Compliance at the Center for Devices and Radiological Health (the "CDRH") within the U.S. Food and Drug Administration ("FDA") from January 2003 until September 2010 at which time I held the position of Senior Advisor for Enforcement until my retirement on January 1, 2011. Including my time as Director of the Office of Compliance in the CDRH, I worked for the FDA for approximately 36 years, and have specialized expertise in matters concerning medical devices and the Office of Compliance in the CDRH. I currently work as a consultant with NDA Partners LLC, a firm that assists pharmaceutical and medical device companies with, among other things, the development of their products.

2. I was retained by Robbins Geller Rudman & Dowd LLP ("Robbins Geller"), Lead Counsel on behalf of the proposed class in a case pending against Baxter International Inc. ("Baxter") and certain of its officers and directors styled, *City of Lakeland Employees Pension Plan v. Baxter International Inc.*, *et al.*, to assist in analyzing factual information on behalf of Plaintiff. I have not provided any non-public documents, proprietary, or confidential information, such as internal FDA or Baxter materials, to Robbins Geller.

3. I submit this Declaration in support of the factual allegations set forth in and underlying Plaintiff's Amended Consolidated Class Action Complaint for Violation of the Federal Securities Laws (the "Amended Consolidated Complaint").

4. I am familiar with the nature of the securities fraud allegations in this case by reviewing public information as well as the Consolidated Class Action Complaint for Violation of the Federal Securities Laws (the "Consolidated Complaint").

5. As the Director of the Office of Compliance at the CDRH, I reported to the Director of the CDRH, Dr. Daniel Schultz ("Dr. Schultz"), from April 2004 until approximately 2009, when Dr. Schultz resigned from the FDA. From approximately September 2009 until my retirement from

the FDA, I reported to Dr. Jeffrey Shuren ("Dr. Shuren"), who replaced Dr. Schultz as the Director of the CDRH.

6. In my capacity as the Director of the Office of Compliance at the CDRH, I was responsible for the management of approximately 200 FDA employees, including compliance officers, engineers, scientists, administrative personnel, and physicians. My primary responsibilities as Director of the Office of Compliance at the CDRH were to ensure that companies complied with federal rules and regulations, including the Code of Federal Regulations, Quality System Regulation, concerning the design and manufacture of medical devices and to initiate actions, on behalf of the FDA, against companies that failed to meet applicable federal laws and regulations.

7. To ensure that companies abide by applicable laws and regulations, the Office of Compliance at the CDRH undertakes actions that are based, in part, on the outcomes of inspections of manufacturing facilities.

8. As a result of my position as Director of the Office of Compliance at the CDRH, I have first-hand experience with Baxter and the various issues surrounding the unsuccessful attempts at remediation of Baxter's Colleague Volumetric Infusion Pump (the "Colleague"). Among other things, I am familiar with the 2006 Consent Decree entered into between Baxter, Robert L. Parkinson, Jr. ("Parkinson"), and the FDA. The Consent Decree established terms and conditions under which Baxter was required not only to remediate its Colleague pumps, but also to address and resolve numerous internal control and quality deficiencies the FDA concluded contributed to the Colleague's numerous design flaws and frequent failures in actual clinical use.

9. I attended numerous meetings between the FDA and Baxter representatives, including Baxter's Chief Executive Officer, Robert L. Parkinson, Jr., wherein Baxter provided information to the FDA concerning the status of the actions Baxter was taking in order to attempt to both comply with the terms of the Consent Decree and to remediate the Colleague pumps.

10. Prior to and throughout the June 10, 2009 through May 3, 2010 "Class Period" alleged in the Amended Consolidated Complaint, the FDA consistently and repeatedly informed Baxter, during face-to-face meetings, on conference calls, and in writing, that its Colleague remediation efforts were insufficient and that Baxter's timeline for remediating the Colleague was unacceptable because the Colleague, at all times, remained a violative device that posed significant and potentially deadly health risks to patients receiving treatment using the Colleague pump in the United States.

11. In that regard, during the Class Period, the Colleague was continuously plagued by a host of problems that included battery and display failures, as well as diagnostic, software, and registry errors, among others. To the extent Baxter created fixes for these and other problems, the nearly universal result was the creation of additional, significant problems with the Colleague pumps. As a result, Baxter was unable to "catch up" to the Colleague's many design and performance deficiencies, and never moved any closer to actually remediating the Colleague pump during the Class Period.

12. Due to Baxter's ongoing failure to remediate the Colleague or to provide the FDA with an acceptable timeline for remediation, at a meeting on November 25, 2008, the FDA informed Baxter that it would be required to submit clinical data to the FDA in any future 510(k) filings for Colleague remediation. Specifically, the FDA required Baxter to submit clinical data because soon after the Company's prior Colleague-related 510(k) submission clearance, Baxter instituted another Colleague recall. Based on my professional experience, it would have taken Baxter at least two years to obtain the necessary clinical data to support future 510(k) submissions for the Colleague. Between late 2008 and the end of the Class Period, Baxter never submitted a proposal to conduct clinical trials for the Colleague and, instead, repeatedly argued for the use of simulated data on the Colleague, a lesser level of scientific accuracy than clinical trials. As a result, Baxter never fully

undertook the necessary steps to obtain the required clinical data demanded by the FDA to demonstrate remediation of the Colleague.

13. By early 2009, the FDA had become intolerant of Baxter's ongoing inability to successfully remediate the Colleague. In that regard, the FDA communicated to Baxter, in writing, in meetings, and on telephone calls, that Baxter's timeline for complying with the Consent Decree was unsatisfactory.

14. Throughout 2009, the FDA consistently and continuously informed Baxter that its remediation timeline was too long and that remediation efforts needed to be expedited. Baxter stated it would provide a revised 510(k) to the FDA by mid-2010. In September 2009, Baxter indicated to the FDA Office of Device Evaluation ("ODE") that the Company would submit its pre-Investigational Device Exemption ("pre-IDE") by the end of September 2009. The pre-IDE was a preliminary step in the required process for Baxter to conduct any clinical trials on the Colleague. Without IDE approval, Baxter could not start the required clinical trials. Prior to the end of September 2009, Baxter informed the FDA's ODE that Baxter's pre-IDE submission would not be made on time. Thereafter, Baxter did not have a meeting with the ODE until January 2010. Because of the clinical data requirement and Baxter's failure to timely submit a pre-IDE, the FDA knew Baxter was unable to present a satisfactory 510(k) for remediation of the Colleague.

15. In addition to Baxter's demonstrated inability to remediate the Colleague, Baxter also continued to experience numerous internal quality deficiencies that were violations of 21 C.F.R. Part 820, the Quality System Regulation. Baxter was aware that without achieving Part 820 compliance, Baxter's ability to generate the clinical data necessary to support a 510(k) submission for Colleague remediation would be compromised, and the Company would remain in violation of the terms of the Consent Decree. Lack of compliance with Part 820 undermined the confidence the FDA's ODE

would have in Baxter's processes for collection, verification, and validation of data submitted in a 510(k).

16. In approximately October 2009, it was clear within the FDA that Baxter had failed to take the appropriate and timely corrective actions to remediate the violative Colleague pumps in use in the healthcare system or to improve Baxter's quality systems to a level that would comply with the terms and conditions of the Consent Decree. Between October 2009 and May 2010, the FDA undertook steps to institute and use a remedy known as "Replacement, Repair, and Refund," or "Triple R," authorized under Section 518(b) of the Food, Drug and Cosmetic Act. While the FDA constructed the Triple R, the Office of Compliance significantly changed the level of dialogue it had with Baxter. When the Office of Compliance greatly reduced the level of substantive dialogue it had with Baxter beginning in October 2009, Baxter and its representatives knew or should have known that the FDA was considering additional punitive actions against Baxter regarding the Colleague.

17. My professional experience with the FDA and interactions with Baxter support my conclusion that the Company and its representatives' statements to the investing public during the time period between June 10, 2009 and May 3, 2010 regarding the Company's dialogue with the FDA and remediation of the Colleague omitted substantial information. The effect of these omissions was to misrepresent to the public both the extent of problems Baxter had in remediating the Colleague and the FDA's reaction to those problems.

18. I have reviewed the allegations attributed to me in the Amended Consolidated Complaint and state that those allegations are true and correct.

19. I declare under penalty of perjury that the foregoing is true and correct. Executed this 14 day of April, 2011, at Herndon, VIRGINIA.

TIMOTHY A. ULATOWSKI

# EXHIBIT B

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ILLINOIS

EASTERN DIVISION

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| CITY OF LAKELAND EMPLOYEES PENSION PLAN, Individually and on Behalf of All Others Similarly Situated,<br><br>Plaintiff,<br><br>vs.<br><br>BAXTER INTERNATIONAL INC., et al.,<br><br>Defendants. | Case No. 1:10-cv-06016<br><br>CLASS ACTION<br><br>DEMAND FOR JURY TRIAL |

**DECLARATION OF BETTY COLLINS IN SUPPORT OF LEAD PLAINTIFF'S AMENDED CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS**

I, Betty Collins, declare:

1. I served as the Director, Division of Enforcement A in the Office of Compliance at the Center for Devices and Radiological Health (the "CDRH") within the U.S. Food and Drug Administration ("FDA") between 1998 and May 2010, when I retired from the FDA. Including my time as the Director, Division of Enforcement A in the Office of Compliance in the CDRH, I worked for the FDA for more than 30 years, and have specialized expertise in matters concerning medical devices and the Office of Compliance in the CDRH. I currently work as a consultant with Betty Collins Consulting LLC, a firm that assists medical device companies with the development of their products and complying with the U.S. FD&C Act and the Safe Medical Devices Act.

2. I was retained by Robbins Geller Rudman & Dowd LLP ("Robbins Geller"), Lead Counsel on behalf of the proposed class in a case pending against Baxter International Inc. ("Baxter") and certain of its officers and directors styled, *City of Lakeland Employees Pension Plan v. Baxter International Inc.*, *et al.*, to assist in analyzing factual information on behalf of Plaintiff. I have not provided any non-public documents, proprietary, or confidential information, such as internal FDA or Baxter materials, to Robbins Geller.

3. I submit this Declaration in support of the factual allegations set forth in and underlying Plaintiff's Amended Consolidated Class Action Complaint for Violation of the Federal Securities Laws (the "Amended Consolidated Complaint").

4. I am familiar with the nature of the securities fraud allegations in this case by reviewing news articles, public information, as well as the Consolidated Class Action Complaint for Violation of the Federal Securities Laws (the "Consolidated Complaint").

5. As the Director, Division of Enforcement A in the Office of Compliance at the CDRH, I reported Timothy A. Ulatowski ("Ulatowski"), the Director of the Office of Compliance at CDRH, and to Dr. Daniel Schultz ("Dr. Schultz") until approximately 2009, when Dr. Schultz

resigned from the FDA. From approximately September 2009 until my retirement from the FDA, I reported to Ulatowksi and Dr. Jeffrey Shuren ("Dr. Shuren"), who replaced Dr. Schultz as the Director of the CDRH.

6. In my capacity as Director, Division of Enforcement A in the Office of Compliance at CDRH, I was responsible for all compliance issues within CDRH, including sending warning letters, all compliance issues, and overseeing enforcement actions on behalf of the FDA.

7. As a result of my position as Director, Division of Enforcement A in the Office of Compliance at CDRH, I have first-hand experience with Baxter and the various issues surrounding the unsuccessful attempts at remediation of Baxter's Colleague Volumetric Infusion Pump (the "Colleague"). Among other things, I am familiar with the 2006 Consent Decree entered into between Baxter, Robert L. Parkinson, Jr. ("Parkinson"), and the FDA. The Consent Decree established terms and conditions under which Baxter was required not only to remediate its Colleague pumps, but also to address and resolve numerous internal control and quality deficiencies the FDA concluded contributed to the Colleague's numerous design flaws and frequent failures in actual clinical use. As the Director, Division of Enforcement A in the Office of Compliance at CDRH, I was primarily responsible for the day-to-day enforcement of the terms and conditions of the Consent Decree on Baxter, which provided me with intimate, first-hand knowledge of Baxter's Colleague remediation efforts and Baxter's quality deficiencies.

8. I attended numerous meetings between the FDA and Baxter representatives, including Baxter's Chief Executive Officer, Robert L. Parkinson, Jr., wherein Baxter provided information to the FDA concerning the status of the actions Baxter was taking in order to attempt to both comply with the terms of the Consent Decree and to remediate the Colleague pumps.

9. Prior to and throughout the June 10, 2009 through May 3, 2010 "Class Period" alleged in the Amended Consolidated Complaint, the FDA consistently and repeatedly informed

Baxter, during face-to-face meetings, on conference calls, and in writing, that its Colleague remediation efforts were insufficient and that Baxter's timeline for remediating the Colleague was unacceptable because the Colleague, at all times, remained a violative device that posed significant and potentially life threatening health risks to patients receiving treatment using the Colleague pump in the United States.

10. In that regard, during the Class Period, the Colleague was continuously plagued by a host of problems that included battery swelling, battery discharge, buffer overflow and the display of several failure codes that led to interruption of therapy, as well as software issues, among others. To the extent Baxter tried to correct these and other problems, their corrections oftentimes resulted in the creation of additional, significant problems with the Colleague pumps. As a result, Baxter was unable to "catch up" to the Colleague's many design defects, performance deficiencies, and flaws, and was never able to demonstrate that Colleague product performance in the clinical settings met Baxter's predicted performance during the Class Period.

11. Due to Baxter's ongoing failure to remediate the Colleague or to provide the FDA with an acceptable timeline for remediation, at a meeting on November 25, 2008, the FDA informed Baxter that it would be required to submit clinical data to the FDA in any future 510(k) filings for Colleague remediation. Specifically, the FDA required Baxter to submit clinical data because soon after the Company's prior Colleague-related 510(k) submission clearance, Baxter initiated another Colleague recall. Between late 2008 and the end of the Class Period, Baxter never submitted a proposal to conduct clinical trials for the Colleague and instead argued for a non-clinical validation data review on the Colleague, a lesser level of review than that required in an investigational clinical trial. As a result, Baxter never fully undertook the necessary steps to obtain the required clinical data demanded by the FDA to demonstrate remediation of the Colleague.

12. By early 2009, the FDA had become intolerant of Baxter's ongoing inability to successfully remediate the Colleague. In that regard, the FDA communicated to Baxter, in writing, in meetings, and on telephone calls, that Baxter's timeline for complying with the Consent Decree was unsatisfactory.

13. Throughout 2009, the FDA consistently and continuously informed Baxter that its remediation timeline was too long and that remediation efforts needed to be expedited. Baxter stated it would provide a revised 510(k) to the FDA by mid-2010. In September 2009, Baxter indicated to the FDA Office of Device Evaluation ("ODE") that the Company would submit its pre-Investigational Device Exemption ("pre-IDE") by the end of September 2009. The pre-IDE was a preliminary step in the required process for Baxter to conduct any clinical trials on the Colleague. Without a IDE approval, Baxter could not start the required clinical trials. Prior to the end of September 2009, Baxter informed the FDA's ODE that Baxter's pre-IDE submission would not be made on time. Thereafter, Baxter did not have a meeting with the ODE until January 2010. Because of the clinical data requirement and Baxter's failure to submit an IDE, the FDA knew Baxter was unable to present a satisfactory 510(k) for remediation of the Colleague.

14. In addition to Baxter's demonstrated inability to remediate the Colleague, Baxter also continued to experience numerous internal quality deficiencies that were violations of 21 C.F.R. Part 820, the Quality System Regulation. Baxter was aware that without achieving Part 820 compliance, Baxter's ability to generate the clinical data necessary to support a 510(k) submission for Colleague remediation would be compromised, and the Company would remain in violation of the terms of the Consent Decree. Lack of compliance with Part 820 undermined the confidence the FDA's ODE would have in Baxter's processes for collection, verification, and validation of data submitted in a 510(k).

15. In approximately October 2009, it was clear within the FDA that Baxter had failed to take the appropriate and timely corrective actions to remediate the violative Colleague pumps in use in the healthcare system or to improve Baxter's quality systems to a level that would comply with the terms and conditions of the Consent Decree. Between October 2009 and May 2010, the FDA undertook steps to initiate a legal action known as "Replacement, Repair, and Refund," or "Triple R," authorized under Section 518(b) of the Food, Drug and Cosmetic Act. While the FDA constructed the Triple R, the Office of Compliance limited the level of dialogue it had with Baxter. The Office of Compliance greatly reduced the level of substantive dialogue it had with Baxter beginning in October 2009, and, rather, encouraged Baxter and its representatives to discuss pre-IDE issues with ODE. Baxter should have known that the FDA was considering additional punitive actions against Baxter regarding the Colleague.

16. My professional experience with the FDA and interactions with Baxter support my conclusion that the Company and its representatives' statements to the investing public during the time period between June 10, 2009 and May 3, 2010 regarding the Company's dialogue with the FDA and remediation of the Colleague omitted substantial information. The effect of these omissions misrepresented information Baxter shared with the public concerning both the extent of problems Baxter had in remediating the Colleague and the FDA's reaction to those problems.

17. I have reviewed the allegations attributed to me in the Amended Consolidated Complaint and state that those allegations are true and correct.

18. I declare under penalty of perjury that the foregoing is true and correct. Executed this 15th day of April, 2011, at Saint George, South Carolina

Betty Collins

BETTY COLLINS